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(54) **SPINOUS PROCESS PLATE FIXATION ASSEMBLY**

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(22) Filed: **Jun. 13, 2022**

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Related U.S. Application Data

(63) Continuation of application No. 16/416,669, filed on May 20, 2019, now Pat. No. 11,382,670, which is a continuation of application No. 15/392,763, filed on Dec. 28, 2016, now Pat. No. 10,335,207.

(60) Provisional application No. 62/273,350, filed on Dec. 30, 2015, provisional application No. 62/272,618, filed on Dec. 29, 2015.

(51) **Int. Cl.**
A61B 17/70 (2006.01)

(52) **U.S. Cl.**
CPC ***A61B 17/7068*** (2013.01); ***A61B 17/7062*** (2013.01)

(58) **Field of Classification Search**
CPC A61F 2/44; A61F 2/4405; A61F 2/4455; A61F 2002/449; A61B 17/7067; A61B 17/7062; A61B 17/7068
USPC 606/246–249; 623/17.11–17.16
See application file for complete search history.

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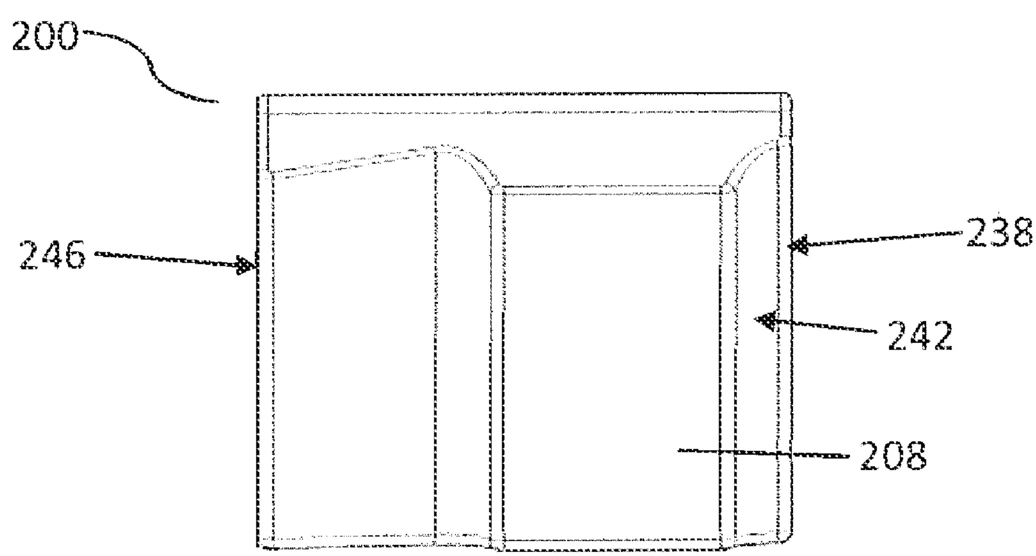
Primary Examiner — Eduardo C Robert
Assistant Examiner — Tara Rose E Carter

(57) **ABSTRACT**

A spinous process plate fixation assembly is provided that has a pin plate including a first central aperture and a pin plate interior surface. The assembly has a lock plate including a second central aperture and a lock plate interior surface opposingly facing the pin plate interior surface. The interior surfaces have a pluralities of spikes extending therefrom. A pin receptacle is disposed within the pin plate and is configured to receive a lock pin. A pivoting lock mechanism is disposed within the lock plate. A connector shaft extends from the pin plate to the lock plate and passes through the first central aperture and the second central aperture. The connector shaft includes a pin side configured to receive the lock pin, and a lock side opposite the shaft side, the lock side configured to operatively engage the pivoting lock mechanism so as to secure the plates and the shaft.

19 Claims, 8 Drawing Sheets



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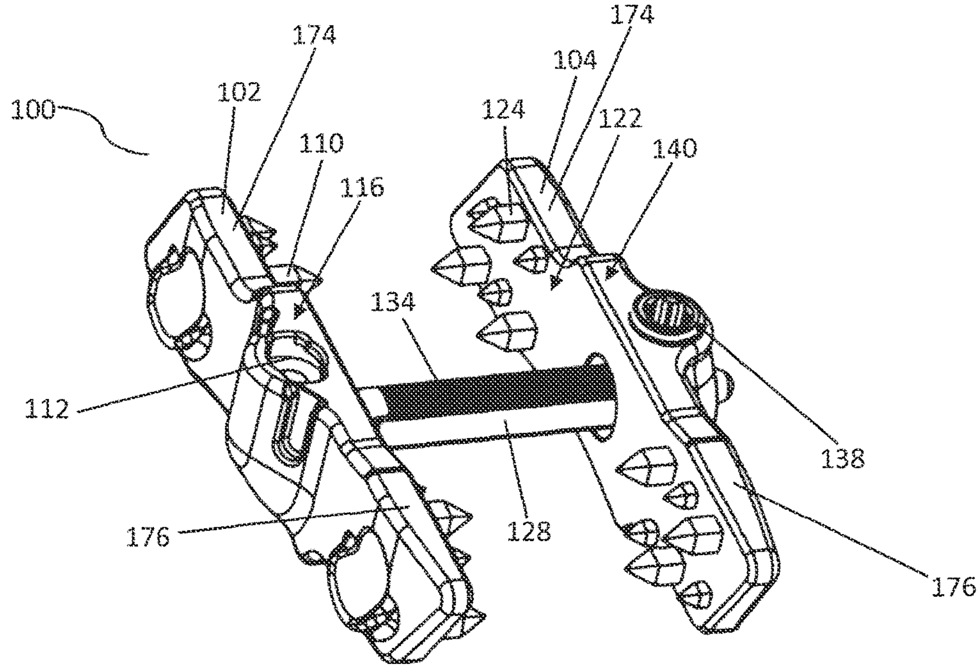
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FIG. 1

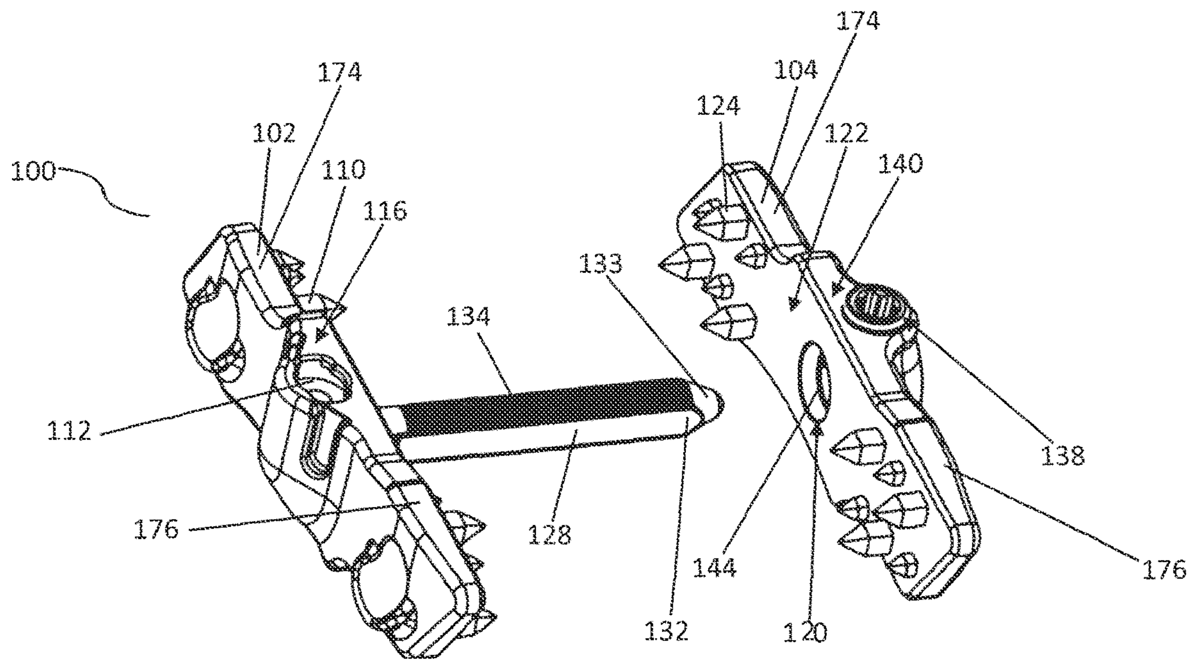
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FIG. 2

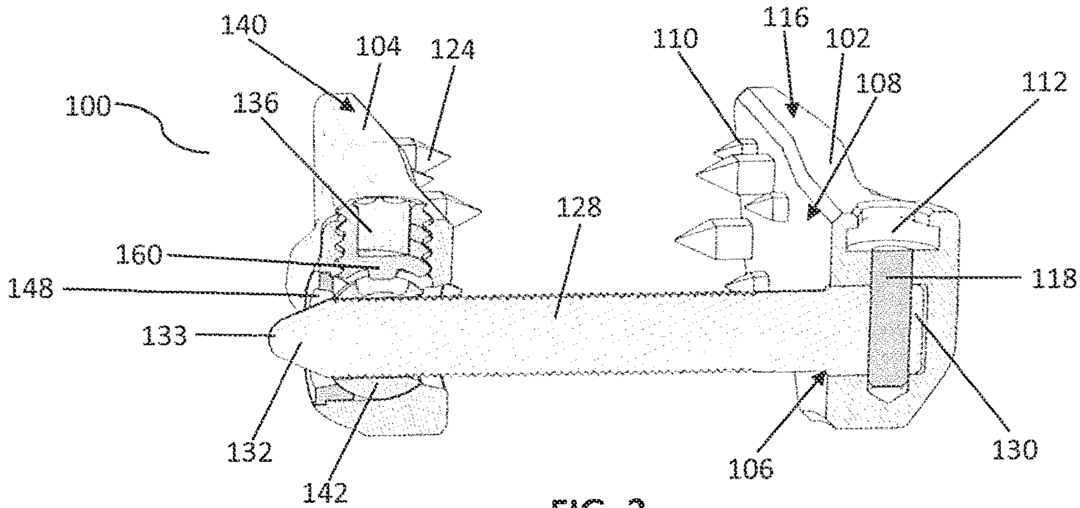

FIG. 3

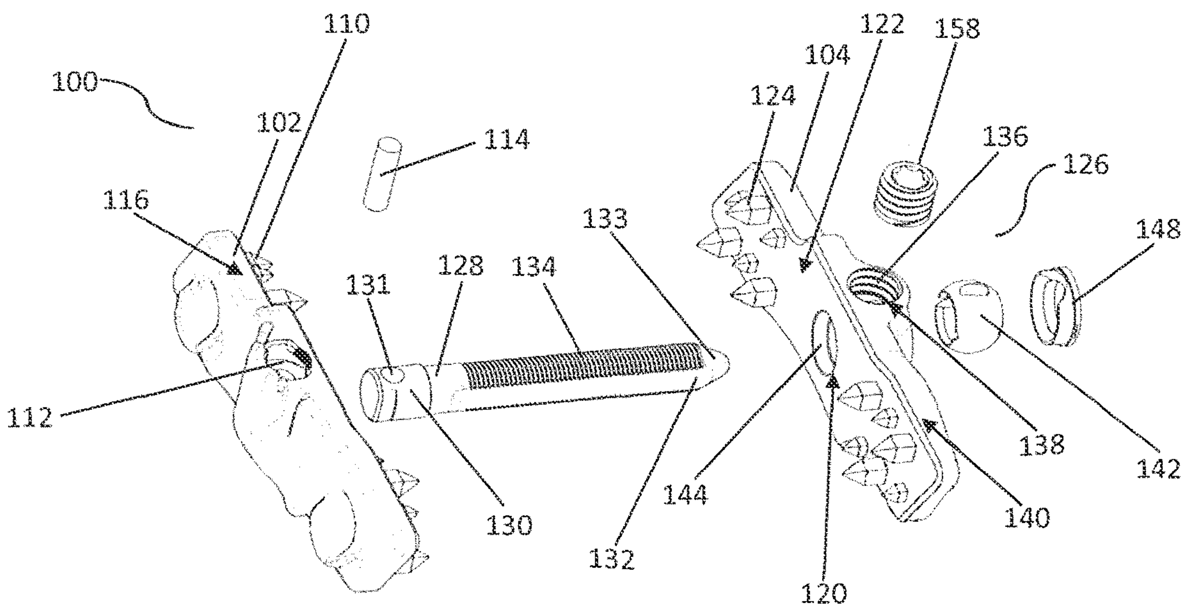

FIG. 4

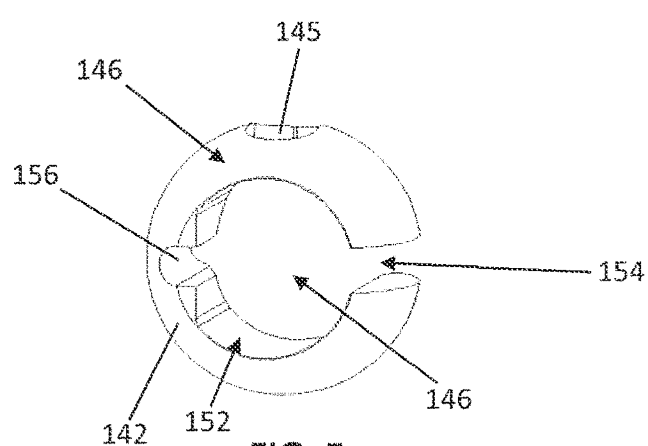

FIG. 5

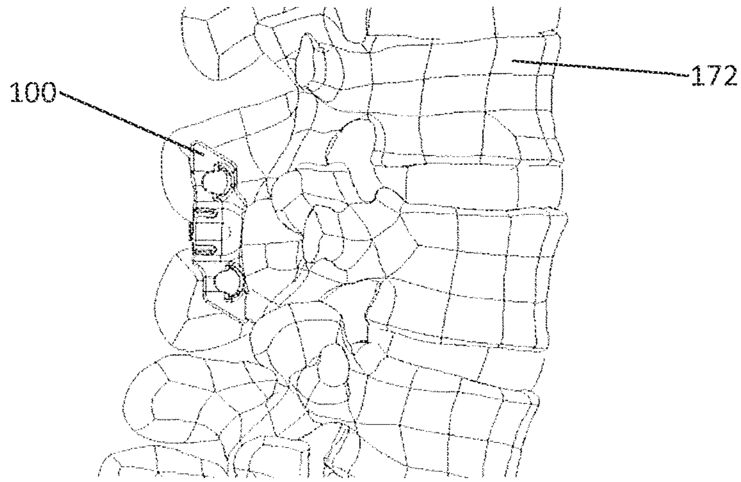

FIG. 6

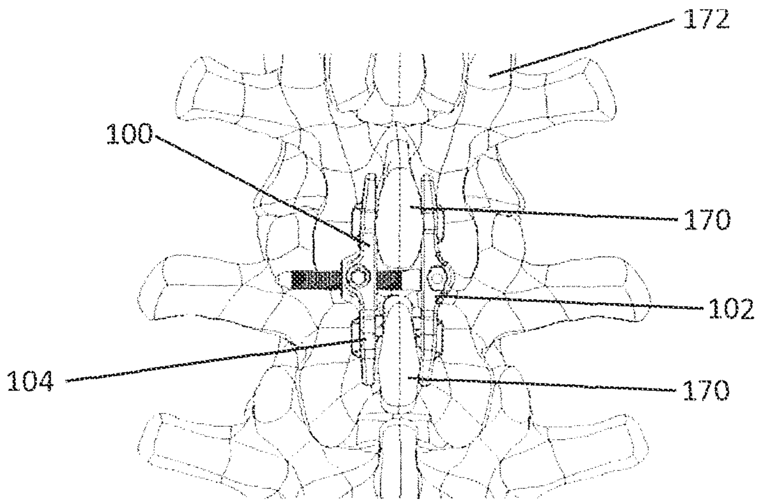

FIG. 7

FIG. 8

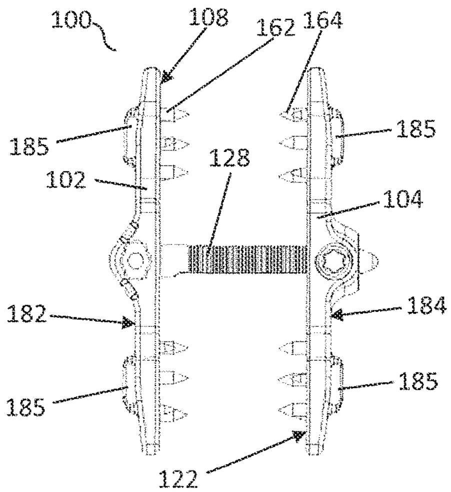

FIG. 9

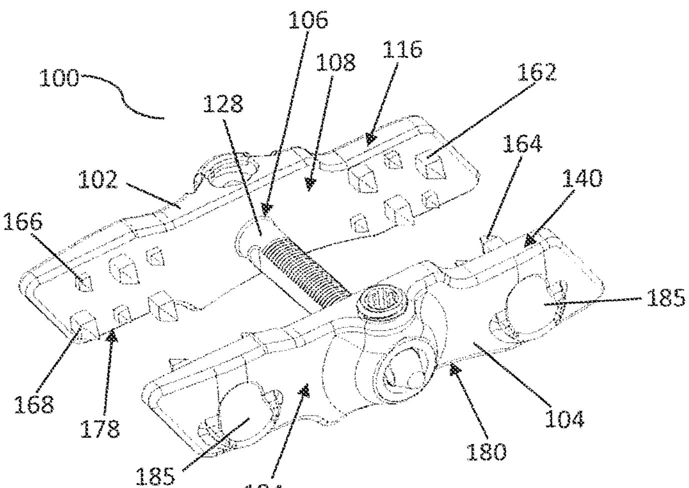

FIG. 10

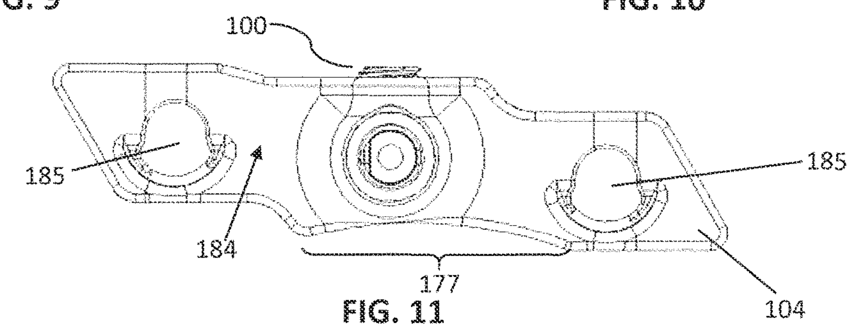

FIG. 11

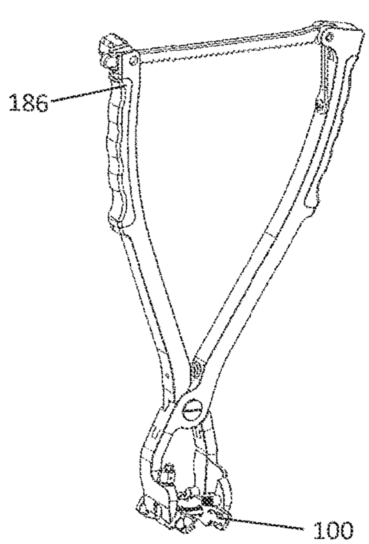

FIG. 12

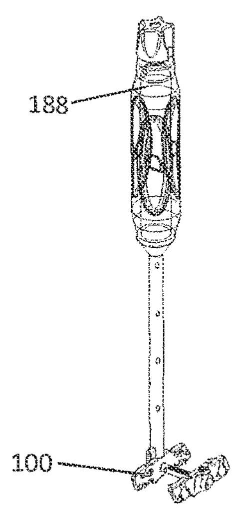

FIG. 13

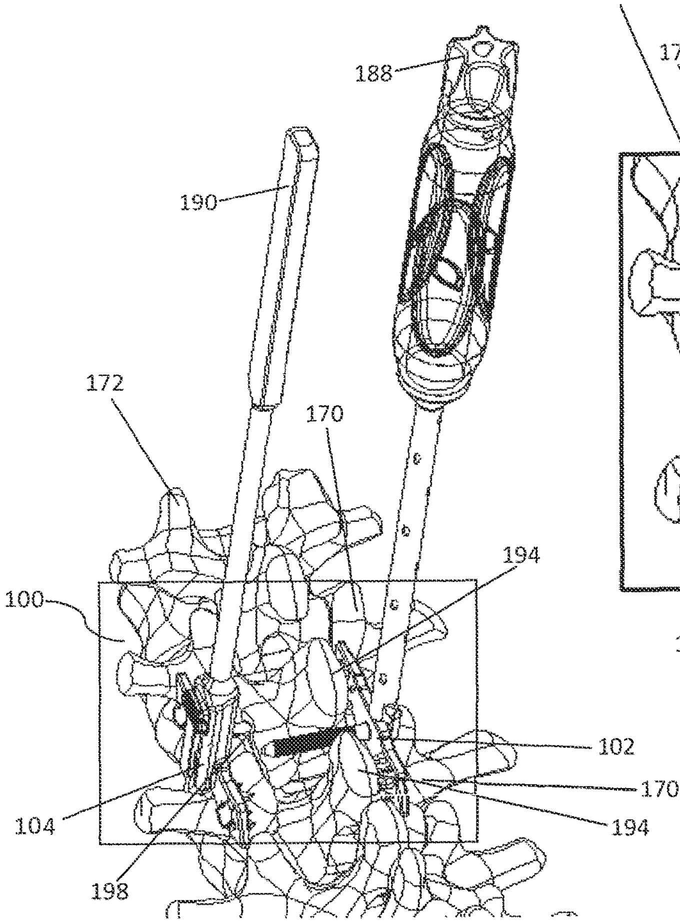

FIG. 14A

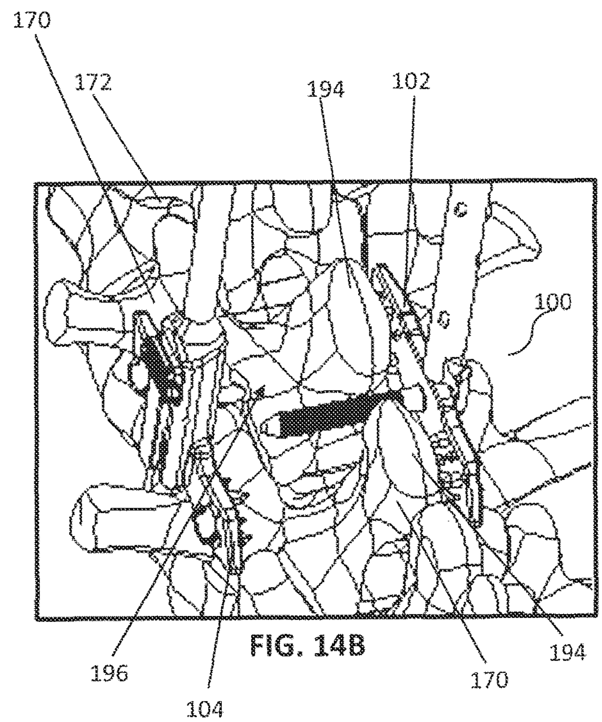

FIG. 14B

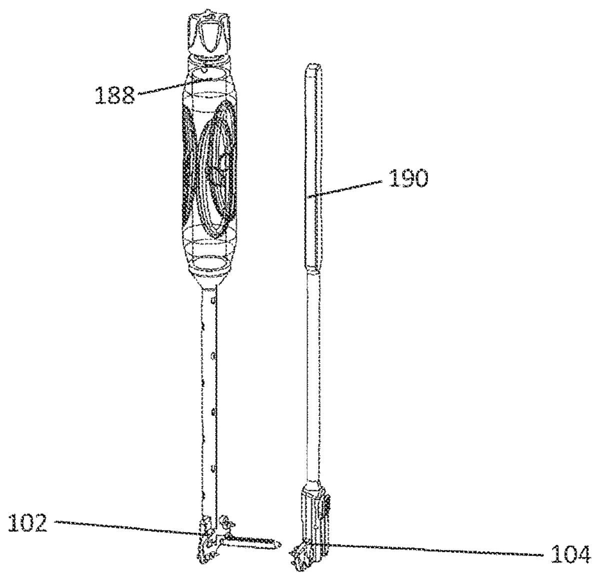

FIG. 15

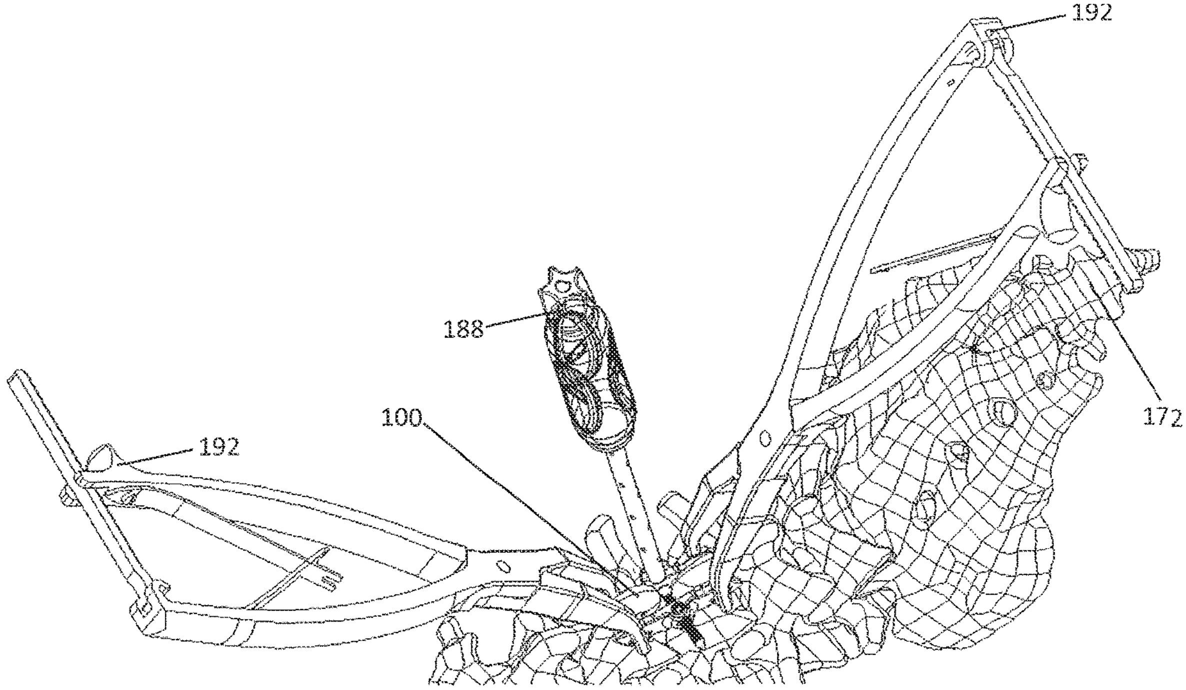

FIG. 16

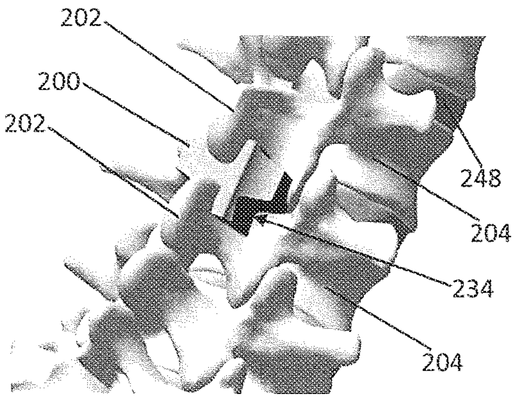

FIG. 17

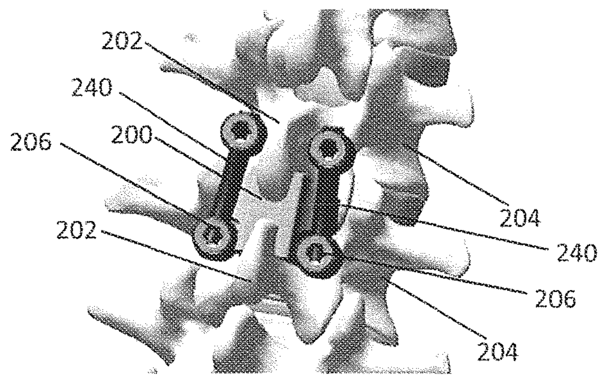

FIG. 18

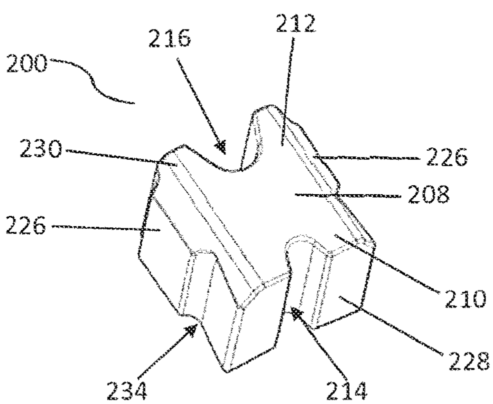

FIG. 19

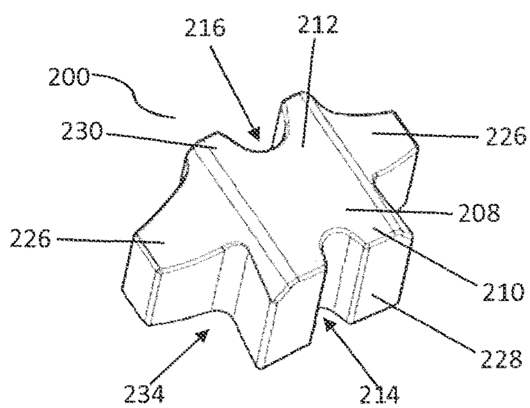

FIG. 20

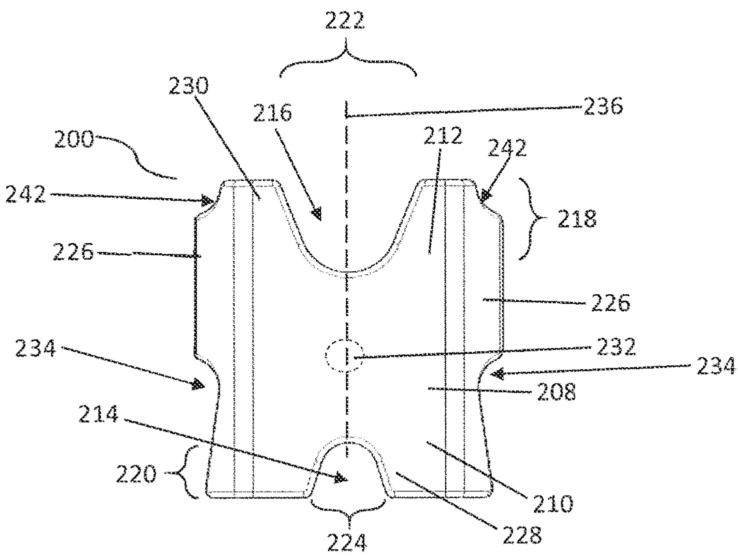

FIG. 21A

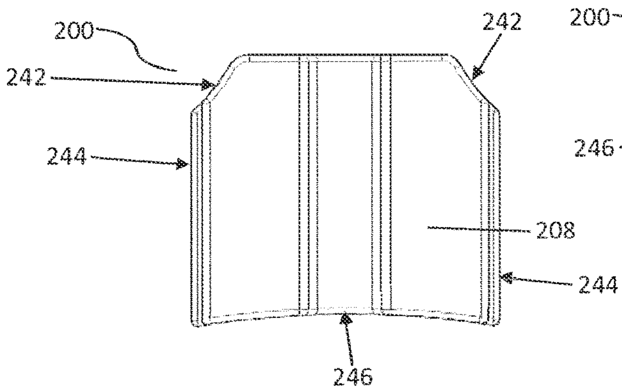

FIG. 21B

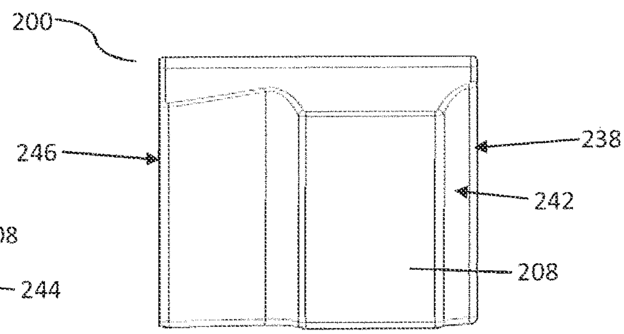

FIG. 21C

SPINOUS PROCESS PLATE FIXATION ASSEMBLY

CROSS REFERENCE TO RELATED APPLICATIONS

The present application is a continuation of U.S. patent application Ser. No. 16/416,669 filed on May 20, 2019, which claims priority to U.S. patent application Ser. No. 15/392,763 filed Dec. 28, 2016, which claims priority to U.S. Provisional Application No. 62/272,618, filed on Dec. 29, 2015, and U.S. Provisional Application No. 62/273,350, filed on Dec. 30, 2015, each of which is entirely incorporated herein by reference.

FIELD

The present disclosure relates generally to medical devices, more specifically to the field of spinal surgery and devices for fusing adjacent spinous processes to stabilize the vertebral segment associated with the particular spinous processes. Such devices as well as systems and methods for use therewith are described.

BACKGROUND

The spinal column is critical in human physiology for mobility, support, and balance. The spine column protects the nerves of the spinal cord, which convey commands from the brain to the rest of the body, and convey sensory information from the nerves below the neck to the brain. The spinal column is made of two basic components—vertebrae (bone) and intervertebral discs (gel-like cushions that absorb pressure and prevent vertebrae from rubbing together). A number of vertebrae and intervertebral discs stack together to form a column that provides support and structure for the body while still allowing a large degree of motion and flexibility and protecting the spinal cord. Even minor spinal injuries can be debilitating to the patient, and major spinal injuries can be catastrophic. The loss of the ability to bear weight or permit flexibility can immobilize the patient. Even in less severe cases, small irregularities in the spine can put pressure on the nerves connected to the spinal cord, causing devastating pain and loss of coordination. Examples of causes of such pain include changes in disc height and improper motion of vertebrae.

Surgical procedures on the spine often include the immobilization of two or more vertebrae, typically by fusing vertebrae together. As a result of such surgical invention, disc height may be corrected, and vertebrae may be immobilized, while fusion occurs.

One of the more common methods for achieving the desired immobilization is through the application of bone anchors (most often introduced into the pedicles associated with the respective vertebrae to be fixed) that are then connected by rigid rods locked to each pedicle screw. A significant challenge with such bone anchors is securing the pedicle screws without breaching, cracking, or otherwise compromising the pedicle wall, which may occur if the screw is not properly aligned with the pedicle axis. Moreover, such pedicle screw systems require invasive surgery. Therefore, a need continues to exist for systems for fusing vertebrae that can be used as alternatives to pedicle screws and can be used in minimally invasive surgical procedures.

SUMMARY

The needs described above, as well as others, are addressed by embodiments of a spinous process plate fixation assembly described in this disclosure (although it is to be understood that not all needs described above will necessarily be addressed by any one embodiment), as the spinous process fixation plate assembly of the present disclosure is separable into multiple pieces and can be assembled in-situ, and thus, can be used in minimally invasive spinal surgeries. Moreover, the assembly of the present disclosure does not rely on a pedicle screw system.

In an aspect, a spinous process plate fixation assembly includes a pin plate and a lock plate. The pin plate has a first central aperture and a pin plate interior surface. The pin plate interior surface has a first plurality of spikes extending therefrom. A pin receptacle is disposed within the pin plate and is configured to receive a lock pin. The lock plate has a second central aperture and a lock plate interior surface opposingly facing the pin plate interior surface. The lock plate interior surface has a second plurality of spikes extending therefrom. A pivoting lock mechanism is disposed within the lock plate. A connector shaft extends from the pin plate to the lock plate and passes through the first central aperture and the second central aperture. The connector shaft includes a pin side configured to receive the lock pin, and a lock side opposite the shaft side, the lock side configured to operatively engage the pivoting lock mechanism.

In an embodiment of the spinous process plate fixation assembly, the lock mechanism includes a threaded channel disposed within a top surface of the lock plate and a lock chamber disposed within the lock plate. A pivoting lock is disposed within the lock chamber and includes a lock slot in communication with the threaded channel. The pivoting lock includes a connector shaft passage configured to receive the lock side of the connector shaft.

In an embodiment of the spinous process plate fixation assembly, each of the first plurality of spikes and the second plurality of spikes include spikes having cuboid-shaped bases and pyramid-shaped tips. The first and second pluralities of spikes may be positioned on offset flat portions of the pin plate and the lock plate, respectively. Each of the pin plate and the lock plate may have two staggered flat portions.

The pin plate and the lock plate may each include an exterior face positioned opposite of the pin plate interior surface and the lock plate interior surface, respectively. Each of the exterior faces may include at least two compressor alignment slots disposed on opposite sides of the connector shaft.

In another aspect, a kit comprises a lock pin and a pin plate including a first central aperture and a shaft plate interior surface, the pin plate interior surface including a first plurality of spikes. A pin receptacle is disposed within the pin plate and configured to receive the lock pin. The lock plate includes a second central aperture and a lock plate interior surface. The lock plate interior surface including a second plurality of spikes. The kit includes a pivoting lock mechanism configured to be received in the lock plate. The kit comprises a connector shaft configured to extend from the pin plate to the lock plate and pass through the first central aperture and the second central aperture. The connector shaft includes a pin side configured to receive the lock pin; and a lock side opposite the shaft side, the lock side configured to operatively engage the pivoting lock mechanism.

The pivoting lock mechanism may include a threaded channel disposed within a top surface of the lock plate, a lock chamber disposed within the lock plate, and a pivoting lock disposed within the lock chamber and including a lock slot in communication with the threaded channel. In an

embodiment, the pivoting lock includes a connector shaft passage configured to receive the lock side of the connector shaft. The pivoting lock may include an exterior toroidal surface and an interior friction fit surface. In some embodiments, the kit includes a lock flange configured to secure the pivoting lock within the lock chamber. The pivoting lock may include a compression slot proximal to the lock slot and opposite from a compression flat configured for orientation when the pivoting lock is compressed. The compression slot may be configured to be reduced when the pivoting lock is compressed.

In an embodiment of the kit, each of the pin plate and the lock plate include at least two staggered flat portions. Each of the pin plate and the lock plate may include an exterior face opposite of the pin plate interior surface and the lock plate interior surface, respectively. Each of the exterior faces may include at least two compressor alignment slots disposed on opposite sides of the connector shaft. The kit may include an instrument selected from the group of an inserter-compressor instrument, a shaft inserter, a single locking tool, a compressor, and combinations thereof.

In another aspect, a midline spinal allograft includes a body having a lower side opposite of an upper side. The lower side has a caudal groove dimensioned to receive a cranial side of a lower spinous process. The upper side has a cranial groove dimensioned to receive a cranial side of an upper spinous process. The cranial groove may have a cranial groove height greater than a caudal groove height of the caudal groove, and the cranial groove may have a cranial groove width greater than a caudal groove width of the caudal groove. At least two lower legs are disposed around the caudal groove, and at least two upper legs are disposed around the cranial groove.

In yet another aspect, a method of producing a demineralized allograft is disclosed herein. The method includes harvesting cancellous bone, cutting the harvested cancellous bone into a predetermined block size, weighing the cut cancellous bone, determining the cut cancellous bone has a mass density greater than a minimum mass density, shaping and sizing the cut cancellous bone to a predetermined shape and size to form a midline spinous allograft, washing the midline spinous allograft, demineralizing the midline spinous allograft in an acid, cleaning the demineralized midline spinous allograft, and packaging the cleaned demineralized midline spinous allograft.

The above presents a simplified summary in order to provide a basic understanding of some aspects of the claimed subject matter. This summary is not an extensive overview. It is not intended to identify key or critical elements or to delineate the scope of the claimed subject matter. Its sole purpose is to present some concepts in a simplified form as a prelude to the more detailed description that is presented later.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** A perspective view of an embodiment of a spinous process plate fixation assembly as assembled for usage.

FIG. **2** A perspective view of the spinous process plate fixation assembly shown in FIG. **1** when disassociated.

FIG. **3** A cross-section view of the spinous process plate fixation assembly shown in FIG. **1**.

FIG. **4** An exploded view of the spinous process plate fixation assembly shown in FIG. **1**.

FIG. **5** A perspective view of the pivoting lock of the spinous process place assembly shown in FIG. **1**.

FIG. **6** A lateral view of the spinous process plate fixation assembly shown in FIG. **1** compressed to a spine in one orientation.

FIG. **7** A posterior view of the spinous process plate fixation assembly and spine shown in FIG. **6**.

FIG. **8** A perspective view of the spinous process plate fixation assembly and spine shown in FIG. **6**.

FIG. **9** A top view of the spinous process plate fixation assembly shown in FIG. **1**.

FIG. **10** An alternate perspective view of the spinous process plate fixation assembly shown in FIG. **1**.

FIG. **11** A side view of the spinous process plate fixation assembly shown in FIG. **1**.

FIG. **12** A perspective view of a combination inserter-compressor instrument holding an assembled spinous process plate fixation assembly shown in FIG. **1**.

FIG. **13** A perspective view of a single shaft inserter holding an assembled spinous process plate fixation assembly shown in FIG. **1**.

FIG. **14**A A perspective view of a ligament sparing surgical technique showing a pin plate through a ligament with a lock plate being introduced into the surgical site with the single shaft inserter and a single locking tool.

FIG. **14**B A magnified view of the pin plate and the lock plate in the ligament sparing surgical technique shown in FIG. **14**A.

FIG. **15** A perspective view of the single shaft inserter and the single locking tool on the spinous process plate fixation assembly shown in FIG. **1** when using the ligament sparing surgical technique.

FIG. **16** A perspective view showing the assembly shown in FIG. **1** being compressed using simple compressors on a spine.

FIG. **17** A perspective view of an embodiment of a midline allograft placed between spinous processes of adjacent lumbar vertebrae.

FIG. **18** A perspective view of the midline allograft of FIG. **17** with posterior fixation elements installed.

FIG. **19** A perspective view of an embodiment of a midline allograft.

FIG. **20** A perspective view of another embodiment of a midline allograft.

FIG. **21**A A top view of the midline allograft of FIG. **20**.

FIG. **21**B A bottom view of the midline allograft of FIG. **20**.

FIG. **21**C A side view of the midline allograft of FIG. **20**.

DETAILED DESCRIPTION

Illustrative embodiments of a spinous process plate fixation assembly and midline spinous process allograft are described below. In the interest of clarity, not all features of an actual implementation are described in this specification. It will of course be appreciated that in the development of any such actual embodiment, numerous implementation-specific decisions must be made to achieve the developers' specific goals, such as compliance with system-related and business-related constraints, which will vary from one implementation to another. Moreover, it will be appreciated that such a development effort might be complex and time-consuming, but would nevertheless be a routine undertaking for those of ordinary skill in the art having the benefit of this disclosure. The spinous process fixation plate assembly, midline spinous process allograft, and related methods disclosed herein boast a variety of inventive features and components that warrant patent protection, both individually and in combination.

As used herein, the term "proximal" means the side facing closest to the surgeon when the device is properly implanted, whereas the term "distal" means the side facing away from the surgeon.

Spinous Process Plate Fixation Assembly

A spinous process plate fixation assembly **100** is provided that includes a pin plate **102** and a lock plate **104**. The pin plate **102** has a first central aperture **106** disposed at, or proximate to, the center of a pin plate interior surface **108**. The pin plate interior surface **108** may be flat or substantially flat. The pin plate interior surface **108** has a first plurality of spikes **110** extending therefrom. A pin receptacle **112** is disposed within the pin plate **102** and is configured to receive a lock pin **114** (FIG. **4**). The pin receptacle **112** may originate in a top surface **116** of the pin plate **102**. The pin receptacle **112** may include a pin chamber **118** that is shaped complementarily to pin **114** such as to receive the pin **114**. The pin chamber **118** may extend vertically through the pin plate **102**.

When joined in the spinous process plate fixation assembly **100** (as shown in FIG. **1**), the lock plate **104** may be positioned laterally opposite of the pin plate **102**. The lock plate **104** has a second central aperture **120** disposed at, or proximate to, the center of a lock plate interior surface **122**. The lock plate interior surface **122** opposingly faces the pin plate interior surface **108** when the assembly **100** is assembled. The lock plate interior surface **122** has a second plurality of spikes **124** extending therefrom. A pivoting lock mechanism **126** is disposed within the lock plate **104**. The pivoting lock mechanism **126** may be in fluid communication with the second central aperture **120**. When assembler **100** is assembled, a connector shaft **128** extends from the pin plate **102** to the lock plate **104** and passes through the first central aperture **106** and the second central aperture **120**, operatively connecting the pin plate **102** and the lock plate **104**, as shown in FIG. **1**.

The connector shaft **128** includes a pin side **130** configured to receive the lock pin **114**, and a lock side **132** opposite the pin side **130**, the lock side **132** being configured to operatively engage the pivoting lock mechanism **126**. The pin side **130** may have a pin lock channel **131** disposed vertically therein that is configured to receive the lock pin **114**. The pin lock channel **131** may be shaped complementary to the lock pin **114**. In one embodiment of the assembly **100**, the pin **114** is welded, or otherwise fixedly attached, to the pin plate **102** such that the pin **114** is secured within both of the pin lock channel **131** of the connector shaft **128** and the pin receptacle **112** of the pin plate **102**. The welding or attachment of pin **114** fixes the connection between the pin plate **102** and the connector shaft **128** such that the connector shaft **128** does not move relative to the pin **114**. In an alternative embodiment of the assembly **100**, the pin **114** is not welded or fixedly attached to the pin plate **102** such that the connector shaft **128** is able to move relative to the pin **114**.

The lock side **132** of the connector shaft **128** may include a tapered tip **133**. When engaged in the lock plate assembly **100**, the tapered tip **133** may extend beyond the outer most surface of the lock plate **104**. Advantageously, the tapered tip **133** enables user-friendly engagement for a surgeon assembling the assembly **100** in-situ. For example, the tapered tip **133** allows the surgeon to easily position the tapered tip **133** with a pre-perforated ligament (not shown) or to create a perforation (not shown) using the tapered tip **133**. The connector shaft **128** may have a plurality of flanges **134**, which may be V-shaped, disposed on its surface for operatively engaging pivoting lock mechanism **126**. The V-shaped flanges **134** increase friction during locking of the assembly **100** due to an interaction with the pivoting lock mechanism **126** and a lock groove **156**.

In an embodiment, as shown in FIGS. **3** and **4**, the pivoting lock mechanism **126** includes a threaded channel **136** disposed vertically through the lock plate **104** and terminating at a lock aperture **138** in a top surface **140** of the lock plate **104**. The lock aperture **138** is open to the threaded channel **136**. A pivoting lock **142**, shown in detail in FIG. **5**, can be disposed in a lock chamber **144** of the lock plate **104** when assembled (as shown in, for example, FIG. **3**) as part of the pivoting lock mechanism **126**. The pivoting lock **142** includes a lock slot **145** that is in fluid communication with the threaded channel **136** of the lock plate **104** when the assembly **100** is assembled (FIG. **3**). The pivoting lock **142** includes a connector shaft passage **146** configured to receive the lock side **132** of the connector shaft **128**. The pivoting lock mechanism **126** includes a lock flange **148** which is configured to be received by the lock chamber **144**, the connector shaft **128**, and the pivoting lock **142**. When the assembly **100** is assembled, as shown in FIGS. **1** and **3**, the lock flange **148** secures the pivoting lock **142** within the lock chamber **144** of the lock plate **104** while allowing the pivoting lock **142** to pivot, or rotate, within the lock chamber **144**.

As shown in FIG. **5**, the pivoting lock **142** may have an exterior toroidal surface **150**. The exterior toroidal surface **150** may be shaped complementary to the lock chamber **144** so that the pivoting lock **142** can be received and rotate within the chamber **144**. The pivoting lock **142** may have an interior friction fit surface **152**. The interior friction fit surface **152** may be shaped complementary to the shape of the connector shaft **128**. As such, the shape of the friction fit surface **152** is laterally flat and has two arcs that continuously curve, interrupted by a compression slot **154** and the lock groove **156**. The compression slot **154** may be positioned proximate to the lock slot **145**, and the lock groove **156** may be positioned opposite of lock groove **156**. Advantageously, when the pivoting lock **142** is compressed in use, the compression slot **154** is reduced, or pinches, to enable the pivoting lock **142** to secure the connector shaft **128** that is disposed within the connector shaft passage **146**. The lock groove **156** provides flexibility in the axis of the reduction such that the compression slot **154** is reduced when vertical force is applied in use. This force may be applied by a threaded locking feature **158**.

The threaded locking feature **158** may have threads configured to operatively engage with threads in the threaded channel **136** of the lock plate **104**. When the threaded locking feature **158** is engaged with the threaded channel **136**, the threaded locking feature **158** travels through the threaded channel **136** to engage and secure the pivoting lock **142**. The threaded locking feature **158** may have a locking tab **160** disposed on its base, the locking tab **160** configured to engage with the locking slot **145** of the pivoting lock **142**. Advantageously, when the threaded locking feature **158** engages and secures the pivoting lock **142**, the pivoting lock **142** is fixed, or secured, in a position, thereby also securing the lock side **132** of the connector shaft **128**.

Advantageously, the pivoting lock mechanism **126** disclosed herein allows the assembly **100** to have nearly infinite variable locking positions with the maximum positions formed by the threaded locking feature **158** and the lock plate **104**. The pivoting lock mechanism **126** allows the lock plate **104** to float around it prior to locking. During compression, the pivoting lock mechanism **126** allows the lock plate **104** to articulate in all directions, and then during locking secures the lock plate **104** in the position found during compression. The compression on the pivoting lock **142** remains the same in any position.

In an embodiment of the assembly **100**, each of the first plurality of spikes **110** and the second plurality of spikes **124** include spikes having cuboid-shaped bases **162** and pyramid-shaped tips **164** (FIGS. **9** and **10**) (which can be described as "house-shaped"). Each of the first plurality of spikes **110** and the second plurality of spikes **124** may have minor (i.e., relatively small) spikes **166** and major (i.e., relatively large) spikes **168**. The house-shaped spikes of varying size increase the bite, or grip, of the spikes on vertebrae **170** of a spine **172** to be immobilized and provide increased resistance, when engaged with the vertebrae **170**, of movement, including caudal, cranial, distal, dorsal and rotational. In particular, engaged pluralities of spikes **110** and **124** provide a high level of torsional micro motion resistance within the bone during flexion/extension movement. The first plurality of spikes **110** and the second pluralities of spikes **124** may each be positioned on a first offset flat portion **174** and a second offset flat portion **176**, respectively, of the plates **102** and **104**. Each of the pin plate **102** and the lock plate **104** may have exactly two staggered flat portions **174** and **176**. The first offset flat portion **174** and the second offset flat portion **176** may be vertically offset, or staged, from one another around the connector shaft **128**. The first flat portion **174** may be defined by a step-down, or drop, in a bottom surface **178** in the pin plate **102** and a bottom surface **180** in the lock plate **104**, and a step-down, or drop in the top surfaces **116** and **140** of the plates **102** and **104**. The second flat portion **176** may be positioned opposite from the first flat portion **174**. The second flat portion **176** may be defined by a step-up, or rise, in a bottom surface **178** in the pin plate **102** and a bottom surface **180** in the lock plate **104**, and a step-up, or rise in the top surfaces **116** and **140** of the plates **102** and **104**. The top surfaces **116** and **140** and the bottom surfaces **178** and **180** are flat, or substantially flat, across the first offset flat portion **174** and the second offset flat portion **176**.

Advantageously, assembly **100** having plates **102** and **104** with flat portions **174** and **176** has a lower profile, which is beneficial for performing minimally invasive surgeries, and is shaped to interface with allograft and/or polyetheretherketone devices. The anterior side of the plates **102** and **104** can include a radiused section **177** configured to interact with the allograft or a polyetheretherketone spacer. The dimensions of the radiused section **177** allow the assembly **100** to be post packed with autograft or allograft after full locking, as the connector shaft **128** and the interior surfaces **108** and **122** create a barrier with which bone chips can easily be packed. Moreover, the lower profile of the disclosed assembly **100** allows the plates **102** and **104** to attach further on a spinous process **194** and to have the pluralities of spikes **110** and **124** compressed into the transition area between the lamina and the spinous process **194**. Furthermore, this profile potentially enables multi-level fixation of vertebrae **170**.

The pin plate **102** and the lock plate **104** may include a pin plate exterior face **182** and a lock plate exterior face **184**, respectively (FIG. **9**). The pin plate exterior face **182** is positioned opposite of the pin plate interior surface **108** on the pin plate **102**, and the lock plate exterior face **184** is positioned opposite of the lock plate interior surface **122** on the lock plate **104**. The at least two compressor alignment slots **185** may be disposed on opposite sides around the connector shaft **128**. Each of the exterior faces **182** and **184** may include at least two compressor alignment slots **185** that extend partially into the exterior faces **182** and **184**.

As shown in FIGS. **12-16**, various tools may engage with the assembly **100** and be utilized in use of the assembly **100**. For example, as shown in FIG. **12**, an embodiment of the assembly **100** can be associated with a combination inserter-compressor instrument **186**. The combination inserter-compressor instrument **186** is configured to simultaneously engage the at least two compressor slots **185** while inserting the lock pin **114** into the pin receptacle **112** and the threaded locking feature **158** into the threaded channel **136** when the assembly **100** is positioned in a subject, such as a human, during spinal surgery.

As shown in FIG. **13**, a single shaft inserter **188** may cooperate with the assembly **100** to insert the lock pin **114** into the pin receptacle **112**. FIG. **14**A illustrates a single locking tool **190** to insert the threaded locking feature **158** into the threaded channel **136**, being used with the single shaft inserter **188** while the assembly **100** is in-use during a spinal surgical procedure, such as a ligament sparing technique. In FIG. **14**A, the pin plate **102** is through a ligament **198**, and the lock plate **104** and the pivoting lock mechanism **126** are being introduced into the surgical site. FIG. **14**B is an enlarged view of the assembly **100** of FIG. **14**A.

FIG. **15** illustrates the single shaft inserter **188** and the single locking tool **190** when using the ligament sparing technique. FIG. **16** illustrates the assembly **100** being assembled and compressed using a pair of simple compressors **192** in a spine **172**.

In an embodiment, a kit is provided that includes the assembly **100**. The kit may include the lock pin **114**, the pin plate **102**, the lock plate **104**, the pivoting lock mechanism **126**, and the connector shaft **128**. The kit may include the threaded locking feature **158**, the pivoting lock **142**, and the lock flange **148**. At least one instrument may be provided in the kit, the instrument selected from the group of: the combination inserter-compressor instrument **186**, the single shaft inserter **188**, the single locking tool **190**, the simple compressor **192**, and combinations thereof.

A method of implanting and facilitating fixation between two spinal vertebrae is provided using the assembly **100** is provided. A posterior midline skin and muscle incision is made between two spinous processes **194** and is opened to the spinal vertebrae **170**. A decompression is performed, and/or an interbody device (not shown) is placed in an intervertebral disc space **196**, and the assembly **100** is placed on the lateral sides of adjacent spinous processes **194** at the treated level, ensuring the pluralities of spikes **110** and **124** on medial facing plates **102** and **104** are engaging bone. The plates **102** and **104** are compressed toward each other, and the pluralities of spikes **110** and **124** are pressed into the spinous processes **194**. The lock plate **104** is then locked down using the pivoting lock mechanism **126**. FIGS. **6**, **7**, and **8** illustrate the assembly **100** locked onto the spine **172**.

Spinal fusion surgical procedures using the disclosed spinous process plate fixation assembly **100** are referred to as ligament sparing type procedures. Advantageously, because the present assembly **100** is separable and is able to be assembled in-situ, as shown in FIGS. **14**A, **14**B, and **15**, the ligament **198** does not need to be removed to use the assembly **100**, enabling the present assembly **100** optimal for less invasive surgical procedures than alternative procedures and devices. During a ligament sparing procedure using the presently disclosed assembly **100**, the pin plate **102** is inserted to the spine **172** and aligned to the first lateral side of two adjacent spinous processes **194**. The lock plate **104** is inserted to the spine **172** and aligned to the opposite lateral side of the two adjacent spinous processes **194**. The plates **102** and **104** are then moved toward each other such that the connector shaft **128** is inserted through the second central aperture **120** in the lock plate **104** and into the pivoting lock **142**. Upon engagement, the plates **102** and **104** are urged toward each other until the pluralities of spikes **110** and **124** are driven into the lateral sides of the adjacent spinous processes **194**. The plates **102** and **104** are urged toward each other until a predetermined level of compression is reached, then the threaded locking feature **158** is engaged to secure the assembly **100** in the fixed position. The threaded locking feature **158** may be engaged, for example, by inserting it into the threaded channel **136** and rotating it so that the threads of the locking feature **158** and the channel **136** cooperate to drive the locking feature **158** into the channel **136**. The instruments disclosed herewith allow separation and assembly through the interspinous ligament **198** without having to remove the ligament **198**.

The assembly **100** may be constructed of any suitable materials, including biocompatible materials. Some embodiments of the assembly **100** are constructed of non-absorbable biocompatible materials. Specific examples of such suitable materials include titanium, alloys of titanium, steel, stainless steel, and surgical steel. The assembly **100**, or parts thereof, could conceivably be made from non-metallic biocompatible materials, which include aluminum oxide, calcium oxide, calcium phosphate, hydroxyapatite, zirconium oxide, and polymers such as polypropylene. The plates **102** and **104** and respective pluralities of spikes **110** and **124** may be integrally formed.

Midline Spinous Process Allograft

As discussed above, the spinous process plate fixation assembly **100** can be used with an allograft, such as a midline spinous process allograft. A midline spinous process allograft **200** is provided herein. When posterior fixation is performed, such as posterior lumbar fusion or posterior lumbar interbody fusion, a postlateral fusion typically extends to the transverse process in order to lay allograft or autograft to create a fusion. However, the allograft **200** of the present disclosure allows for the creation of a fusion without extending past the facets, enabling a less invasive surgical procedure compared to alternatives.

As shown in FIGS. **17** and **18**, the allograft **200** is configured to be positioned between spinous processes **202** of lumbar and/or thoracic vertebrae **204** during a spinal fusion surgical procedure. As shown in FIG. **18**, the allograft **200** can be used in conjunction with pedicle screw systems **206**. The midline spinal allograft includes a body **208** having a lower side (i.e., distal side) **210** opposite of an upper side **212** (i.e., proximal side). The lower side **210** has a caudal groove **214** dimensioned to receive a cranial side of the lower spinous process **202**. The upper side **212** has a cranial groove **216** dimensioned to receive a caudal side of the upper spinous process **202**. The cranial groove **216** may have a cranial groove height **218** greater than a caudal groove height **220** of the caudal groove **214**. The cranial groove **216** may have a cranial groove width **222** greater than a caudal groove width **224** of the caudal groove **214**. The larger cranial groove **216** allows the allograft **200** to reach the lamina of the vertebra **204** of the spinous process **202**, allowing for more, or enhanced, fusion. As shown in FIG. **17**, the allograft **200** is positioned for an L2 to L3 vertebrae **204** fusion.

The midline spinal process allograft **200** includes two lateral wings **226**, each wing **226** disposed on opposite sides of the body **208**. At least two lower legs **228** are disposed around the caudal groove **214**, and at least two upper legs **230** are disposed around the cranial groove **216**. The lower legs **228** and upper legs **230** are disposed on opposite sides of the body **208** and are proximate to the wings **226**. The lower legs **228** may taper inwardly toward the caudal groove **214** such that each of the legs **228** has a lower leg surface **250** shaped complementary to laminar for improved laminar contact.

The lateral wings **226** may be dimensioned to extend a distance that is further from the body **208** than a distance that the lower legs **228** extend, as shown in FIG. **20**. In an alternate embodiment, shown in FIG. **19**, the lateral wings **226** may be dimensioned to extend a distance that is proximal from the body **208** than a distance that the lower legs **228** extend. Advantageously, in embodiments of the allograft **200** having lateral wings **226** that extend a distance that is further from the body **208** than a distance that the lower legs **228** extend, the wider wings **226** are capable of extending to a facet joint **248** of the vertebrae **204**, allowing an increased amount of scaffold to incorporate a bone fusion. Moreover, wider wings **226** allow the wings to go more anterior to allow rod passage of the rod **240** above the allograft **200**.

In an embodiment of the midline spinal process allograft **200**, the cranial groove **216** continuously tapers inwardly away from the upper legs **230** and toward a center **232** of the body **208**. Similarly, the caudal groove **214** may continuously taper inwardly away from the lower legs **228** and toward the center **232** of the body **208**.

The midline spinal process allograft **200** may have at least two caudal bone fixator spaces **234** dimensioned to receive a caudal bone fixator, such as the pedicle screw system **206**. Each of the at least two caudal bone fixator spaces **234** is defined by the area between the lower legs **228** and the lateral wings **226**. In an embodiment of the midline spinal allograft **200**, the allograft **200** may be vertically symmetrical around a center plane **236**.

The body **208** includes a top face **238** and lateral sides **244**, the top face **238** and lateral sides **244** each forming a junction **242** dimensioned to receive a rod **240**, such as the rod **240** of the pedicle screw system **206**, shown in FIG. **18**, positioned parallel to the junction **242**. The junctions **242** may continuously curve from the top face **238** to the lateral sides **244** such that the junctions **242** are shaped complementary to the rod **240**.

The allograft **200** may include a distal face **246** that continuously curves inwardly away from the lateral sides **244** and toward the center point **232** of the body **208**. The distal face **246** may be dimensioned and shaped for spinal dura clearance after decompression of a spine **172** when the allograft **100** is in use in a subject. The shape and dimensions of the allograft **200**, including the grooves **214** and **216** and the legs **228** and **230**, allows enhanced compression to occur between the vertebrae.

The allograft **200** may be fully demineralized or partially demineralized, or used without any demineralization. The allograft **200** may be dimensioned to fit several different anatomies, such as that of an adult, child, male, or female human. In embodiments of the allograft **200** that are demineralized, the allograft **200** may fit a larger range of subject sizes that that of a mineralized allograft, increasing surgeon convenience and technique. A kit may be provided having a plurality of allografts **200**, each having varying sizes so that a surgeon may select the optimal patient-specific allograft **200**.

In yet another aspect, a method of producing a demineralized midline spinous allograft, such as the allograft **200** of the present disclosure, is disclosed herein. The method includes harvesting cancellous bone, cutting the harvested cancellous bone into a predetermined block size, weighing the cut cancellous bone, determining the cut cancellous bone has a mass density greater than a minimum mass density, shaping and sizing the cut cancellous bone to a predetermined shape and size to form a midline spinous allograft, washing the midline spinous allograft, demineralizing the midline spinous allograft in an acid, cleaning the demineralized midline spinous allograft, and packaging the cleaned demineralized midline spinous allograft. The packaging may include freezing drying or packaging in saline. In embodiments having packaging in saline, the graft is dried, and bone marrow aspirate is taken from a patient and soaked into the demineralized allograft.

The harvesting may from a source of cancellous bone such as a condyle of a femur bone of a human. The cancellous bone may be shaped with a manual machine, such as a hand router, or a computer-controlled cutting machine. The minimum mass density may be about 0.8 g/cm.sup.3. The acid may be hydrochloric acid. A plurality of demineralized midline spinous allografts using the method of demineralization disclosed herein. The plurality of demineralized would be produced having different predetermined shapes and sizes such that a surgeon can select a patient specific midline spinous allograft from the plurality of demineralized midline spinous allografts for use during spinal surgery of the patient.

It is to be understood that any given elements of the disclosed embodiments of the invention may be embodied in a single structure, a single step, a single substance, or the like. Similarly, a given element of the disclosed embodiment may be embodied in multiple structures, steps, substances, or the like.

The foregoing description illustrates and describes the processes, machines, manufactures, compositions of matter, and other teachings of the present disclosure. Additionally, the disclosure shows and describes only certain embodiments of the processes, machines, manufactures, compositions of matter, and other teachings disclosed, but, as mentioned above, it is to be understood that the teachings of the present disclosure are capable of use in various other combinations, modifications, and environments and are capable of changes or modifications within the scope of the teachings as expressed herein, commensurate with the skill and/or knowledge of a person having ordinary skill in the relevant art. The embodiments described hereinabove are further intended to explain certain best modes known of practicing the processes, machines, manufactures, compositions of matter, and other teachings of the present disclosure and to enable others skilled in the art to utilize the teachings of the present disclosure in such, or other, embodiments and with the various modifications required by the particular applications or uses. Accordingly, the processes, machines, manufactures, compositions of matter, and other teachings of the present disclosure are not intended to limit the exact embodiments and examples disclosed herein. Any section headings herein are provided only for consistency with the suggestions of 37 CFR 1.77 or otherwise to provide organizational queues. These headings shall not limit or characterize the invention(s) set forth herein.

What is claimed is:

1. A midline spinous process allograft, comprising:

a body including a lower side, an upper side opposite the lower side, a top face, a distal face opposite the top face, and a pair of lateral sides opposite one another;

two lower legs disposed on the lower side;

a caudal groove disposed between the two lower legs;

two upper legs disposed on the upper side;

a cranial groove disposed between the two upper legs;

a lateral wing disposed on each of the pair of lateral sides of the body and proximate to the two lower legs and two upper legs,

a junction disposed above each lateral wing, each junction extending from the top face to the distal face, wherein each junction is curved from the upper side to one of the lateral wings.

2. The midline spinous process allograft of claim **1**, wherein the caudal groove is dimensioned to receive a cranial side of a lower spinous process.

3. The midline spinous process allograft of claim **1**, wherein the cranial groove is dimensioned to receive a caudal side of an upper spinous process.

4. The midline spinous process allograft of claim **1**, wherein the cranial groove is larger than the caudal groove.

5. The midline spinous process allograft of claim **1**, wherein the caudal groove has a first height, and the cranial groove has a second height that is greater than the first height.

6. The midline spinous process allograft of claim **1**, wherein the caudal groove has a first width, and the cranial groove has a second width that is greater than the first width.

7. The midline spinous process allograft of claim **1**, wherein the two lower legs taper inwardly toward the caudal groove, such that the two lower legs form a shape that is complementary to a lamina of a vertebra.

8. The midline spinous process allograft of claim **1**, wherein the lateral wing disposed on each of the pair of lateral sides extends a first distance from the body, and the two lower legs each extend a second distance from the body that is less than the first distance.

9. The midline spinous process allograft of claim **1**, wherein the lateral wing disposed on each of the pair of lateral sides extends a first distance from the body, and the two lower legs each extend a second distance from the body that is greater than the first distance.

10. The midline spinous process allograft of claim **1**, wherein the cranial groove tapers inwardly away from the two upper legs toward a center of the body.

11. The midline spinous process allograft of claim **1**, further comprising two caudal bone fixator spaces that are dimensioned to receive a caudal bone fixator.

12. The midline spinous process allograft of claim **11**, wherein the caudal bone fixator is a pedicle screw system.

13. The midline spinous process allograft of claim **11**, wherein each of the two caudal bone fixator spaces are positioned between one of the two lower legs and one of the pair of lateral wings.

14. The midline spinous process allograft of claim **1**, wherein each junction is dimensioned to complement an adjacent rod, the curved surface extending between the top face and a respective one of the pair of lateral sides.

15. The midline spinous process allograft of claim **1**, wherein the distal face is configured to curve inwardly away from the pair of lateral sides toward a center of the body.

16. The midline spinous process allograft of claim **15**, wherein the distal face is dimensioned for spinal dura clearance after decompression of a spine.

17. The midline spinous process allograft of claim **1**, wherein the allograft is vertically symmetrical around a center plane.

18. The midline spinous process allograft of claim **1**, wherein the allograft is fully demineralized or partially demineralized.

19. A kit comprising:

two or more midline spinous process allografts of claim **1**, wherein each of the two or more midline spinous process allografts in the kit is sized and configured for use in a subject of a different size.

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